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## Evaluating the Clinical Impact of Providing Home Blood Pressure Monitors to Patients with Elevated or High Blood Pressure

Theresa La Guardia Asmus

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## ABSTRACT

### EVALUATING THE CLINICAL IMPACT OF PROVIDING HOME BLOOD PRESSURE MONITORS TO PATIENTS WITH ELEVATED OR HIGH BLOOD PRESSURE

Many clinicians continue to diagnose hypertension based on office-based readings, despite the 2015 United States Preventive Services Task Force recommendation for the use of home or ambulatory blood pressure monitoring to confirm the diagnosis of hypertension prior to initiating treatment. Without obtaining blood pressure readings outside of the clinic environment, it is impossible to correctly diagnose hypertension, particularly regarding masked hypertension and white coat hypertension.

Stanford Health Care implemented a quality improvement project that provided patients with a home blood pressure device to monitor out of clinic blood pressure readings. The purpose of the project was to improve clinical care at Stanford Health Care, to assess for treatment control in patients already diagnosed with hypertension, and to verify the diagnosis of hypertension in patients undiagnosed. There were 98 subjects who had elevated or high blood pressure readings in the clinic who agreed to participate in the project. Findings showed that home blood pressure monitoring was effective in assessing for hypertension treatment control and verifying hypertensive phenotype in previously undiagnosed patients. Home blood pressure monitoring also allowed for timely diagnosis and treatment of hypertension. Providing home blood pressure devices to patients has the potential to reduce morbidity and mortality related to hypertension, reduce economic burden, and contribute to national quality initiatives that contribute to the overall health of the nation.

Theresa Asmus  
May 2020



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HOME BLOOD PRESSURE MONITORS TO PATIENTS WITH  
ELEVATED OR HIGH BLOOD PRESSURE

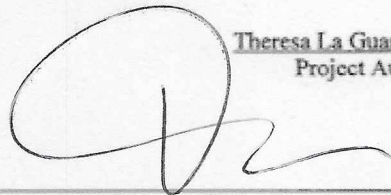
by  
Theresa La Guardia Asmus

A project  
submitted in partial  
fulfillment of the requirements for the degree of  
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California State University, Northern Consortium  
Doctor of Nursing Practice  
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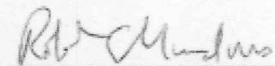
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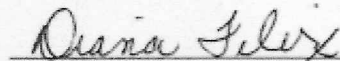
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## CHAPTER 1: INTRODUCTION

Management of hypertension is a public health challenge. Approximately 1 in 3 United States adults has hypertension (Centers for Disease Control (CDC), 2016). New hypertension screening guidelines published in 2017 by the American Heart Association (AHA) and the American College of Cardiology (ACC) aggressively defines hypertension as having a systolic blood pressure (SBP) greater than 130 mmHg or a diastolic blood pressure (DBP) greater than 80 mmHg. The stricter definition of hypertension resulted in a substantial increase in prevalence of United States adults with hypertension, which increased from 31.1% to 45.6% based on data from the 2011 to 2014 National Health and Nutrition Examination Survey (NHANES) (Muntner et al., 2018). Currently, of the United States adults with the diagnosis of hypertension, 47.8% have blood pressure control, which is far below the target of Healthy People 2020's Leading Health Indicator initiative of having achieved 61.2% blood of pressure control (Office of Disease Prevention and Health Promotion (ODPHP), 2019).

Many clinicians continue to diagnose hypertension based on clinic readings despite the 2015 United States Preventive Services Task Force (USPSTF) recommendation that out of clinic blood pressure measurements should be obtained in order to confirm the diagnosis of hypertension before starting pharmacologic treatment, unless contraindicated (Siu, 2015). The 2017 AHA and ACC guideline also recommends utilization of home or ambulatory blood pressure monitoring to confirm the diagnosis of hypertension (Whelton et al, 2018). These changes were implemented to take into account the limitations to blood pressure measurement in the clinic setting, including incorrect blood pressure measuring techniques, improper training of medical staff, limited number of clinic readings

available to make a definitive diagnosis, and the inability to monitor the natural changes in blood pressure over a 24-hour period (White & Gulati, 2015).

Furthermore, by relying on clinic blood pressure measurements, it is impossible to correctly diagnose hypertension, particularly in regard to white coat hypertension and masked hypertension (Whelton et al., 2018). White coat hypertension refers to patients having high blood pressure in the clinic, but normal measurements in their natural environment (Siu, 2015). Masked hypertension is when a patient has normal blood pressure readings in the clinic, but high measurements in the ambulatory setting (Siu, 2015). Without home blood pressure monitoring, there is no way to identify patients with white coat hypertension or masked hypertension, resulting in misdiagnosis of hypertension.

Stanford Health Care implemented a quality improvement project to improve clinical care and address the problem of misdiagnosis of hypertension due to lack of home blood pressure monitoring. Staff created a patient-centered, standardized blood pressure screening workflow using the health belief model as a theoretical framework to inform the workflow design. Patients who presented to the clinic with elevated or high blood pressure readings were provided a home blood pressure monitor, detailed information about high blood pressure and the consequences of untreated hypertension, and instruction on how to use the monitor at home. For patients already diagnosed with hypertension on anti-hypertensive medication, the home blood pressure monitor was provided to assess for treatment control. For patients undiagnosed with hypertension, the home blood pressure monitor was provided to confirm if the patient had normotension, sustained hypertension, white coat hypertension, or masked hypertension. A retrospective chart review was performed to evaluate the clinical impact of providing home

blood pressure monitors to patients with elevated or high blood blood pressure readings in the clinic setting.

### **Background and Significance**

High blood pressure, or hypertension, is the most common chronic condition seen in an ambulatory setting in the United States (National Center for Health Statistics, 2015). Often called the silent killer because there are often no physical symptoms associated with high blood pressure, the consequence of untreated hypertension is target organ damage, which includes stroke, vision loss, heart attack, heart failure, kidney disease, sexual dysfunction, and peripheral arterial disease (AHA, 2016). In 2014, high blood pressure was a primary or contributing cause of death in the United States resulting in 1,100 deaths each day (CDC, 2016). Worldwide, it is estimated that 7.5 million deaths are the result of hypertension; this represents about 12.8% of all total deaths (World Health Organization, 2019).

Hypertension is a major modifiable risk factor for cardiovascular disease and all-cause mortality (Whelton et al, 2018). Modifiable risk factors in patients with hypertension include cigarette smoking or secondhand smoking, diabetes mellitus, dyslipidemia, alcohol consumption, being overweight or obese, physical inactivity, excess stress, and poor diet choices, particularly ones high in sodium (AHA, 2017; Whelton et al, 2018). Common hereditary and physical risk factors include the presence of chronic kidney disease, diabetes, family history of hypertension, increased age, low socioeconomic status, male sex, obstructive sleep apnea, and psychosocial stress (AHA, 2017; Whelton et al, 2018).

High blood pressure is associated with a heavy economic burden. The cost of health care services, medications for treatment, and missed days of work related

to hypertension costs the United States 48.6 billion dollars each year (CDC, 2016). The AHA projected that the cost of care for hypertension will increase to a total projected annual cost of 200.3 billion dollars in 2030, which is a 286% increase from 2010 (Heidenreich et al, 2011).

With the added responsibility of national quality health initiatives pushing for better blood pressure control, it is crucial that patients who have hypertension or who are at risk for developing hypertension learn to monitor their blood pressure at home. Healthy People is a well-known national initiative managed by the Office of Disease Prevention and Health Promotion. Every ten years, Healthy People sets measurable objectives and goals driven by best available knowledge and literature to improve practice and the health of the nation (ODPHP, 2019). There are six objectives in Healthy People 2020 related to high blood pressure, one of which is considered a Leading Health Indicator. This priority issue is to achieve 61.2% blood pressure control amongst United States adults diagnosed with hypertension. In 2008, only 43.7% of United States adults with hypertension had their blood pressure under control. The 2013-2016 NHANES data showed control to only be at 47.8%, far below the target of 61.2% (ODPHP, 2019).

### **National Guidelines**

Over the last twenty years, there have been three guidelines published in the United States for hypertension prevention and management. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) was published in 2003 (see Table 1). A coalition of 39 professional organizations and 7 federal agencies convened to review observational studies and clinical trials to create a guideline for clinicians to classify and treat hypertension (Chobanian et al., 2003). Methodology was

through nonsystematic literature review and recommendations were based on expert committee consensus (James et al., 2014). Pharmacologic treatment of hypertension, according to JNC 7, was initiated at Hypertension Stage 1, when the patient had a SBP of 140 mmHg or a DBP of 90 mmHg, unless they had diabetes or chronic kidney disease. Patients with diabetes or chronic kidney disease had more aggressive treatment guidelines in which their goal SBP was less than 130 mmHg and their goal DBP was less than 80 mmHg (Chobanian et al., 2003). The guideline includes a brief discussion regarding the use of ambulatory or home blood pressure monitoring to evaluate for white coat hypertension, as well as a short excerpt on lifestyle modifications (Chobanian et al., 2003). In regard to pharmacologic treatment, JNC 7 recommended thiazide diuretics as the first-line treatment for hypertension (Chobanian et al., 2003).

Table 1

*2003 JNC 7 Hypertension Guidelines: Blood Pressure Categories*

Blood Pressure Category	Systolic (mmHg)		Diastolic (mmHg)
Normal	Less than 120	AND	Less than 80
Prehypertension	120 – 139	OR	80 - 89
Hypertension Stage 1	140 - 159	OR	90 - 99
Hypertension Stage 2	160 or higher	OR	100 or higher
Hypertensive Crisis	180 or higher	OR	120 or higher

In 2014, the Eighth Joint National Committee (JNC 8) reviewed and synthesized scientific evidence from randomized controlled trials to revise JNC 7 (James et al., 2014). The definition for hypertension remained the same at a SBP of 140 mmHg and a DBP of 90 mmHg. The JNC 8 guideline increased the



threshold goal for patients with diabetes and chronic kidney disease to the same as the general population, at a SBP of 140 mmHg and a DBP of 90 mmHg (James et al., 2014). The only group whose goal was different than the general population were adults 60 years of age or older, in which their goal was specified at a SBP less than 150 mmHg and a DBP less than 90 mmHg (James et al., 2014). In addition to thiazide diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and calcium channel blockers were added for use as first-line treatment for hypertension (James et al., 2014).

A systematic review by the AHA, ACC, and the National Heart, Lung, and Blood Institute (NHLBI) led to the publication of the 2017 Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (Whelton et al., 2018). It was intended as an update to the 2003 JNC 7 guideline. The guideline aggressively lowers the threshold for the diagnosis of hypertension to a SBP of 130 mmHg and a DBP of 80 mmHg in the general population, despite medical history, age, or comorbidities (see Table 2) (Whelton et al., 2018). The terminology ‘elevated blood pressure’ replaced ‘prehypertension,’ also with a lower threshold in definition (see Table 2). Treatment parameters varied, with a large emphasis on lifestyle modifications through diet, exercise, alcohol restriction, and smoking cessation in all patients regardless of their blood pressure category (Whelton et al., 2018). This was the first guideline that recommended calculating the ten-year cardiovascular risk score when considering pharmacologic treatment for patients with Hypertension Stage 1 (Whelton et al., 2018). This was also the first guideline whose blood pressure screening workflow included the use of home or ambulatory blood pressure monitoring to consider the diagnoses of white coat hypertension and masked hypertension (Whelton et al., 2018).

Table 2

*2017 AHA / ACC Hypertension Guidelines: Blood Pressure Categories*

Blood Pressure Category	Systolic (mmHg)		Diastolic (mmHg)
Normal	Less than 120	AND	Less than 80
Elevated Blood Pressure	120 – 129	AND	Less than 80
High Blood Pressure (Hypertension) Stage 1	130 – 139	OR	80 – 89
High Blood Pressure (Hypertension) Stage 2	140 or higher	OR	90 or higher
Hypertensive Crisis	180 or higher	OR	120 or higher

**Theoretical Framework: The Health Belief Model**

The health belief model was developed by social psychologists Hochbaum, Kegels, and Rosenstock in the 1950s (Hochbaum et al, 1952). This was a time when public health programs were being implemented but underutilized. Despite the availability of low or no cost health programs, the population was not participating in preventive initiatives, including influenza and polio vaccinations, cervical cancer screening, and tuberculosis screening (Rosenstock, 1974). The health belief model aimed to explain why patients chose to participate in or withdraw from services by exploring the beliefs and attitudes that influenced decision making (Hochbaum et al., 1952). Since the 1950s, the health belief model has evolved beyond utilization in preventive health and has been used to explain and predict behavior directed toward compliance in treatment of chronic illness. The health belief model is composed of six main concepts, all of which influence a person's readiness to act or change their behavior. These concepts are perceived

susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action, and self-efficacy (Glanz et al., 2018).

Specific to hypertension, the health belief model has been used in literature to study medication adherence, health promotion, and to help inform educational programs for hypertension. A cross-sectional study in a rural city in Iran found that only 24% of a sample of 671 participants with hypertension adhered to their medication regimen (Kamran et al., 2014). The patients more likely to adhere to their treatment plan were patients who perceived that they were susceptible to having hypertension, and that the benefit of treatment outweighed their perceived severity of having hypertension. Results showed the value and importance of patient perceptions on hypertension and medication. Education should be individualized and tailored according to patient perceptions in order to improve medication adherence. Thalacker (2011) used the health belief model as a tool to understand Hmong culture and what influenced their behaviors related to hypertension treatment. Through the health belief model, she was able to suggest an educational program facilitated by health care providers geared to empower the Hmong people to choose health-promoting behaviors related to hypertension (Thalacker, 2011).

For this quality improvement project, the health belief model was used as a theoretical framework to help guide Stanford Health Care's blood pressure screening workflow. The health care team evaluated each of the concepts within the health belief model to inform the design of the blood pressure screening workflow. In doing so, the workflow was designed to inspire participation in the quality improvement project, as well as empower patients to actively engaged in their health by learning how to monitor and understand their blood pressure readings in hopes to trigger healthy lifestyle choices.

### **Perceived Susceptibility and Perceived Severity**

Perceived susceptibility refers to a person's belief in the likelihood of having a disease or condition (Glanz et al., 2018). Patients who have hypertension generally feel well without any noticeable symptoms. Because of this, there is little motivation for patients who have hypertension, or who are at risk for developing hypertension, to comply with pharmacologic treatment or lifestyle modification recommendations. In order for patients to act, they must accept that they may be susceptible to hypertension and its sequelae. The hypertension screening workflow takes this into account by educating every participant during their clinic visit on the meaning of hypertension and the consequences of target-organ damage if left untreated.

### **Perceived Benefits and Perceived Barriers**

Perceived benefits refer to the belief that taking action toward prevention or treatment of disease will reduce a person's susceptibility or severity of the disease (Glanz et al., 2018). The treatment for hypertension includes lifestyle modifications and health promotion in every patient regardless of what stage hypertension they have. Pharmacologic intervention is recommended in patients with Hypertension Stage 2, or in patients with Hypertension Stage 1 with certain comorbidities or a high cardiovascular risk score (Whelton et al., 2018). Treatment adherence is dependent on the patient believing that the benefits of treatment outweigh the barriers and risks. The hypertension screening workflow eliminates three common barriers in home blood pressure monitoring: the out of pocket cost of a home blood pressure device, the concern of correct usage, and the concern of accurate calibration (Kronish et al., 2017; Tirabassi et al., 2013). The device is provided to the patient at no cost, the patient is taught how to utilize the home

blood pressure device, return demonstration of use in the clinic is encouraged, and the device calibration is validated against the clinic automated device in the clinic in front of the patient.

### **Cue to Action**

Cue to action refers to internal or external factors that influence one to take action (Glanz et al., 2018). The cue to action for this quality improvement project is the clinic intervention of providing patients with home blood pressure monitors. As the patient monitors their blood pressure at home, they witness first-hand the variations in their blood pressure readings, whether they are normal or high. This awareness cues them to take their blood pressures seriously, prompting them to make the changes needed to prevent or treat their high blood pressure.

### **Self-Efficacy**

Self-efficacy refers to the confidence in an individual to successfully perform an action or behavior change (Glanz et al., 2018). Self-efficacy is an important concept in hypertension management. In giving a patient a home blood pressure monitor, the clinic promotes self-efficacy by actively engaging the patient in their health. In promoting self-efficacy, the patient becomes confident in self-care, has an understanding of their home blood pressure readings and implications of untreated high blood pressure, and is empowered to execute lasting lifestyle changes to reduce their cardiovascular risk.

## CHAPTER 2: LITERATURE REVIEW

Literature was sought to investigate patient and provider barriers to home blood pressure monitoring, prevalence and risk factors associated with masked and white coat hypertension, and the clinical significance for diagnosing masked and white coat hypertension.

### **Home and Ambulatory Blood Pressure Devices**

There are two approved devices to measure blood pressure readings outside of the clinic setting: ambulatory blood pressure monitoring (ABPM) and home blood pressure monitoring (HBPM) (Shimbo et al., 2015). ABPM measures blood pressure every fifteen to thirty minutes over a 24-hour period during daily routine activities, whereas, HBPM assesses blood pressure at specific times while the person is seated and resting. ABPM and HBPM provide data used to calculate mean out-of-clinic blood pressure in order to identify a person's hypertensive phenotype. There are four primary hypertensive phenotypes: normotension, sustained hypertension, white coat hypertension and masked hypertension (Shimbo et al., 2015).

The final recommendation statement for high blood pressure screening in adults from the USPSTF confirms that there is more evidence that supports ABPM as superior to HBPM; however, if ABPM is unavailable HBPM is an acceptable alternative (Siu, 2015). Since this statement released in 2015, hypertension guidelines have increasingly supported the use of HBPM in the management of hypertension, including the European Society of Hypertension 2018 guideline, the United States AHA and ACC 2017 guideline, and the United Kingdom National Institute for Health and Care Excellence guideline (NICE) (Williams et. Al, 2018; Whelton et al., 2018; NICE, 2019).

### **Challenges of Ambulatory Blood Pressure Monitoring**

There are barriers to consider when utilizing ABPM for both the primary care provider and the patient. Primary care providers voiced concerns regarding the cost of ABPM, willingness or ability of the patient to successfully complete testing, and concerns about the accuracy and benefits of testing (Kronish et al., 2017). ABPM is not widely available in primary care settings, often requiring a referral to a hypertension center or office that has the capacity to perform the test (White & Gulati, 2015). Insurance companies do not always reimburse for ABPM and the reimbursement rate is low (Kent et al., 2014). The perception of primary care providers regarding the lack of patient willingness for testing is disputed in Carter et al.'s qualitative study. Patients voiced that having the option for ABPM or HBPM was an opportunity for them to engage in their care and because of this, they would agree to testing if recommended by the primary care provider (Carter et al., 2018). Patients want to actively participate in their health; however, this is difficult to do without time and resources provided by their primary care. Barriers described on the patient side included testing reliability and concerns regarding night-time blood pressure readings as being disruptive (Carter et al., 2018). Common reported disadvantages from participants who underwent ABPM included pain, skin irritation, bruising, and interference with sleep, so much so that some patients removed the device during the night (Viera et al., 2011).

### **Challenges of Home Blood Pressure Monitoring**

Home blood pressure devices are more widely available than ABPM, as they can be purchased in retail stores and pharmacies. Like ABPM, there are barriers to consider in respect to the primary care provider and patient. Primary care providers voiced concerns regarding compliance with correct methodology

for blood pressure measurement, accuracy of test results, out of pocket costs for the devices, and the time needed to instruct patients on home blood pressure monitoring protocol (Bonafini and Fava, 2015; Kronish et al., 2017). Physicians also voiced concerns about the use of non-validated HBPM and the potential for patient preoccupation in blood pressure monitoring which may lead to anxiety (Cheng et al, 2003; Logan et al., 2008). HBPM allows for more data points over a longer period of time, which may be an advantage or disadvantage. ABPM only provides short-term blood pressure variability over 24-hours, which may not be an appropriate time frame for diagnosis of this chronic condition (Bonafini & Fava, 2015; White & Gulati, 2015). Patients primary concern regarding HBPM was the out of pocket cost if the device was not covered by insurance (Carter et al., 2018; CDC, 2013). Because of this, many patients preferred to have ABPM over HBPM if it was covered by their insurance, to minimize out of pocket costs (Carter et al., 2018; CDC, 2013).

## **White Coat Hypertension**

### **Prevalence**

White-coat hypertension was first described in United States literature in 1984 (Kleinert et al., 1984). Epidemiologic data through the USPSTF estimates that 15 to 30% of United States adults have white coat hypertension (Piper et al., 2015).

### **Risk Factors**

It is proposed that white coat hypertension is due to sympathetic nervous system activation during encounters with health care providers (Grassi et al., 2013). Similarly, Bloomfield and Park attribute the white-coat effect to a neuro-



endocrine reflex conditioned by anticipation of having one's blood pressure taken and fear of what the measurement may indicate (2017). Another determinant of white coat hypertension is age, with patients over the age of 60 at higher risk of having white coat hypertension compared to younger participants (Tanner et al., 2016).

### **Screening**

Current USPSTF hypertension screening recommendations and the 2017 AHA and ACC guideline recommends screening for white coat hypertension with ABPM or HBPM for any patient with elevated or high blood pressure readings in the clinic setting (Siu, 2015; Whelton et al., 2018).

## **Masked Hypertension**

### **Prevalence**

Masked hypertension is a newly appreciated phenomenon, first mentioned in United States literature in 2002 (Pickering et al., 2002). Wang et al. pooled data from the Masked Hypertension study and the NHANES to understand the burden of masked hypertension on the United States (2017). Based on the data, they estimated that 12.3% of United States adults have masked hypertension (Wang et al., 2017). If this data is accurate, then about 1 in every 8 United States adult with normal or elevated blood pressure in the clinic actually has masked hypertension, resulting in millions of adults misclassified as not having hypertension. This is the only study that provides an estimate of masked hypertension prevalence in the United States. A systematic review of five population-based studies, four in Europe and one in Japan, found prevalence of masked hypertension in the general population to range anywhere between 14% to 30% (Peacock et al., 2014).

## **Risk Factors**

The risk factors for masked hypertension are consistent with the risk factors for sustained hypertension. The Jackson Heart Study evaluated masked hypertension in a community-based cohort of African Americans residing in Jackson, Mississippi (Bromfield et al., 2016). Life's Simple 7 questionnaire was used to identify modifiable risk factors and included body mass index (BMI), physical activity, diet, cigarette smoking, clinic-measured blood pressure, total cholesterol, and a fasting glucose. Of the participants, 30.5% had masked hypertension. Masked hypertension was more likely to occur in patients who had worse overall cardiovascular health: poor physical activity, positive smoking status, prehypertension, and poor diet (Bromfield et al., 2016). Similarly, in two separate studies, persons with a sedentary lifestyle, obesity, and low exercise tolerance were prone to having masked hypertension (Schultz et al., 2011; Sharman et al., 2011).

Additionally, alcohol consumption, caffeine consumption, and cigarette smoking are risk factors for masked hypertension (Franklin et al., 2015). Stress or job strain also contributed to normal or elevated blood pressure readings in the clinic but high blood pressure readings outside of the clinic setting (Landsbergis et al., 2013). Conditions that have been linked to masked hypertension include metabolic syndrome, diabetes mellitus, chronic kidney disease, and obstructive sleep apnea (Franklin et al., 2015).

There is conflicting data whether age is a predictor for masked hypertension. Data solely from the Masked Hypertension Study found that of the 888 healthy, middle-aged, employed participants not on medication for hypertension, the prevalence of phenotypes was 79.8% with normotension, 14.9% for masked hypertension, 1.0% with white-coat hypertension, and 4.3% with

sustained hypertension (Schwartz et al., 2016). The majority of patients with masked hypertension were young adults (Schwartz et al., 2016). On the other hand, masked hypertension was found to be more prevalent among older adult males and in patients with prehypertension or diabetes from data pooled from both the Masked Hypertension Study and the NHANES (Wang et al., 2017).

A common predictor for masked hypertension was the presence of elevated blood pressure, formerly known as prehypertension, in the clinic setting (Shimbo et al., 2012; Redmond et al., 2016). Of the patients diagnosed with masked hypertension in the Masked Hypertension Study, 35% had a borderline elevated blood pressure reading in the clinic setting and only 8.9% of the patients had normal clinic blood pressure measurements (Shimbo et al., 2012). Similarly, of the patients diagnosed with masked hypertension in the Improving the Detection of Hypertension Study, 35.3% had elevated blood pressure readings in the clinic setting compared to 6.8% with normal clinic blood pressure measurements (Redmond et al., 2016).

## **Screening**

Literature does not offer clear criteria on whom to screen to detect masked hypertension. Data was pooled from the Masked Hypertension Study, the Improving the Detection of Hypertension Study, and the Jackson Heart Study to determine the practicality of what parameters to use to screen for masked hypertension (Booth et al., 2016). Screening all patients with normal clinic blood pressure readings would result in 118.6 million (~78%) United States adults to undergo ABPM. On the other hand, if elevated clinic blood pressure was used as the criterion to screen for masked hypertension, 59.3 million (~39%) United States adults would undergo ABPM. If the upper range of prehypertension was used as

the criterion for masked hypertension screening, then 20.3 million (13%) United States adults would undergo ABPM. Alternatively, instead of using clinic blood readings as the sole criterion for masked hypertension screening, the practitioner can take a different approach by only screening patients who have more risk factors associated with masked hypertension (Booth et al., 2016). At this point, the ACC/AHA guideline recommends screening patients for masked hypertension using ABPM or HBPM if there is suspicion for masked hypertension and the patient has elevated blood pressure readings in the clinic (a SBP between 120 to 129 mmHg and a DBP less than 80 mmHg) (Whelton et al., 2017).

### **Clinical Significance of White Coat Hypertension and Masked Hypertension**

Masked hypertension is associated with increased adverse cardiovascular outcomes and target organ damage. Patients within the Jackson Heart Study who had masked hypertension compared to normotension had increased arterial, cardiac, and renal damage compared to patients with normotension as measured by carotid artery intima-media thickness, left ventricular mass index, and urinary albumin to creatinine excretion ratio, respectively (Diaz et al, 2014). Similarly, in a large, multiethnic, probability-based population cohort in the Dallas Heart Study, masked hypertension was associated with increased aortic stiffness, renal injury, and cardiovascular events as measured from aortic pulse wave velocity, cystatin C, and urinary albumin-to-creatinine ratio (Tientchu, 2015).

There is conflicting evidence on whether or not white-coat hypertension is associated with higher cardiovascular risk. A study that investigated the cardiovascular outcomes in sustained hypertension, white coat hypertension, and normotension in the short and long term found increased cardiac and cerebrovascular risk in patients with sustained hypertension, but no significant

difference between this risk in patients with white coat hypertension versus normotension (Pierdomenico et al., 2008).

More recent literature shows increasing evidence suggesting that white coat hypertension results in poor cardiovascular outcomes. Similar to masked hypertension, patients with white coat hypertension in the Dallas Heart Study were identified to have evidence of target organ damage with increased aortic stiffness, renal injury, and cardiovascular events (Tientchu, 2015). A comprehensive meta-analysis examining target organ damage and its association with white coat hypertension found higher risk of cardiovascular disease and total mortality in patients with untreated white coat hypertension (Huang et al., 2017). A recent systematic review and meta-analysis published in the *Annals of Internal Medicine* found that untreated white coat hypertension is associated with a near double risk of cardiovascular events and all-cause mortality (Cohen et al., 2019).

### **Summary**

The literature suggests that blood pressure screening strategies that rely solely on clinic blood pressure readings will misdiagnose patients with or without hypertension in regard to white coat and masked hypertension. Incorporating ABPM or HBPM in hypertension screening is necessary to correctly diagnose hypertensive phenotype. Almost all of the studies described in the literature review were performed prior to the publication of the 2017 AHA and ACC guideline on blood pressure management, therefore, data may actually underestimate the prevalence of hypertension in the general population. The literature published after the 2017 AHA and ACC guideline showed increasing evidence of poor cardiovascular outcomes associated with white coat hypertension. The 2017 guideline lacks recommendations for treatment of white coat hypertension.

The studies on provider and patient attitudes regarding ABPM and HBPM are outdated, and no studies have been performed to address these barriers. Further studies are needed to identify better screening parameters for masked hypertension. There are no studies that evaluate the role of ABPM or HBPM in guiding anti-hypertensive treatment. Studies are needed to examine treatment options and outcomes specific to patients with masked hypertension and white coat hypertension.

## CHAPTER 3: METHODOLOGY

To address the problem of misdiagnosis of hypertension due to lack of home blood pressure monitoring, Stanford Health Care implemented a quality improvement project that provided patients with a home blood pressure device to monitor out of clinic blood pressure readings. The purpose of the project was to improve clinical care at Stanford Health Care by using home blood pressure monitoring as a way to assess for treatment control in patients already diagnosed with hypertension, or to verify the diagnosis of hypertension in patients not previously diagnosed.

Stanford Health Care staff created a patient-centered, blood pressure screening workflow mirroring the 2017 AHA and ACC Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. The Stanford School of Medicine sponsored 30 brachial Omron 10 series blood pressure devices (Model: BP7450) to use for the quality improvement project. This model had been inspected and cleared by the United States Food and Drug Administration (FDA) and clinically validated according to protocols from the European Society of Hypertension – International Protocol and the Association for the Advancement of Medical Instrumentation (Omron, 2020).

The workflow was implemented on January 2, 2019. Data was collected from the start of workflow implementation through August 31, 2019. Before collecting data, clinical site permission and institutional review board approval was obtained from both California State University (CSU) Fresno and Stanford School of Medicine. The quality improvement project was exempt from full review by the Committee for the Protection of Human Subjects from both CSU Fresno and Stanford School of Medicine because the project involved the study of

existing data, documents, and records routinely available to the investigator. Only the minimum data necessary for project evaluation was collected. Data was de-identified and obtained from the patient electronic charts on-site on an encrypted computer, only accessible to the investigator. After data analysis completed, the collection log was permanently deleted. The data elements that were collected were clinic blood pressure, clinic phenotype, mean home blood pressure, home phenotype, age, sex, smoking status, BMI, alcohol status, whether the patient was on treatment for hypertension or not, and the time (days) from clinic visit to diagnosis and treatment plan.

### **Subjects**

The subjects were full time employees of a large tech company. They all had health insurance and received care at their employer-based health clinic managed by Stanford Health Care. The professional spectrum included engineers, scientists, lawyers, and business strategists, ages 23 to 66.

### **Inclusion Criteria**

Because of the limited amount of home blood pressure monitors that were available, the quality improvement project was limited to patients who presented to the clinic for their routine preventative physical or for a blood pressure specific complaint. Patients with a clinic blood pressure reading that was considered elevated (SBP greater than 120 mmHg and a DBP greater than 75 mmHg) or high (SBP greater than 130 mmHg or DBP greater than 80 mmHg) were considered for inclusion (see Appendix A for workflow diagram). Patients excluded from borrowing a blood pressure device from the clinic were patients with normal blood pressures (SBP less than 120 mmHg and DBP less than 80) and patients who presented to the clinic for a problem-focused visit that was not blood pressure



specific. Patients were given the option whether or not they wanted to utilize a clinic provided home blood pressure monitor or purchase their own blood pressure device for monitoring. Data was only collected from the patients who chose to borrow the clinic blood pressure device.

### **Workflow**

For patients who presented to the clinic with a blood pressure specific complaint or for their routine preventative health physical, the patient was brought into the clinic room and asked to sit quietly for five minutes. The medical assistant took the patient's blood pressure with Stanford Health Care electronic equipment. If the clinic reading met the criteria for inclusion, the medical assistant automatically re-checked the blood pressure with an Omron home blood pressure monitoring device. Quality was accurate if the diastolic blood pressure was  $\pm 3$  mmHg according to manufacturer standards. If the calibration was not according to manufacturer standards, quality was checked on a different Omron device. After verification that the Omron blood pressure device was correctly calibrated with the electronic equipment, the medical assistant notified the provider that the patient was ready for examination and eligible for HBPM based on clinic blood pressure measurement.

During the office visit, the provider discussed the findings and implications of elevated or high blood pressure with the patient, and the need for confirmation of diagnosis through HBPM. Additionally, the patient was given instruction on lifestyle changes to improve blood pressure measurements. The patient was given the option to either purchase a blood pressure device or borrow the clinic Omron cuff to obtain out of clinic blood pressure measurements in order to confirm diagnosis of hypertension. The patient was then instructed on the proper way to

take their blood pressure at home using the Omron blood pressure device. It was recommended that the patient take three consecutive blood pressure readings. The first reading was to be discarded, and the average of the second and third reading was to be recorded into a blood pressure log. They were asked to do this twice daily, preferably before breakfast and before dinner, for at least three consecutive days after resting for five minutes.

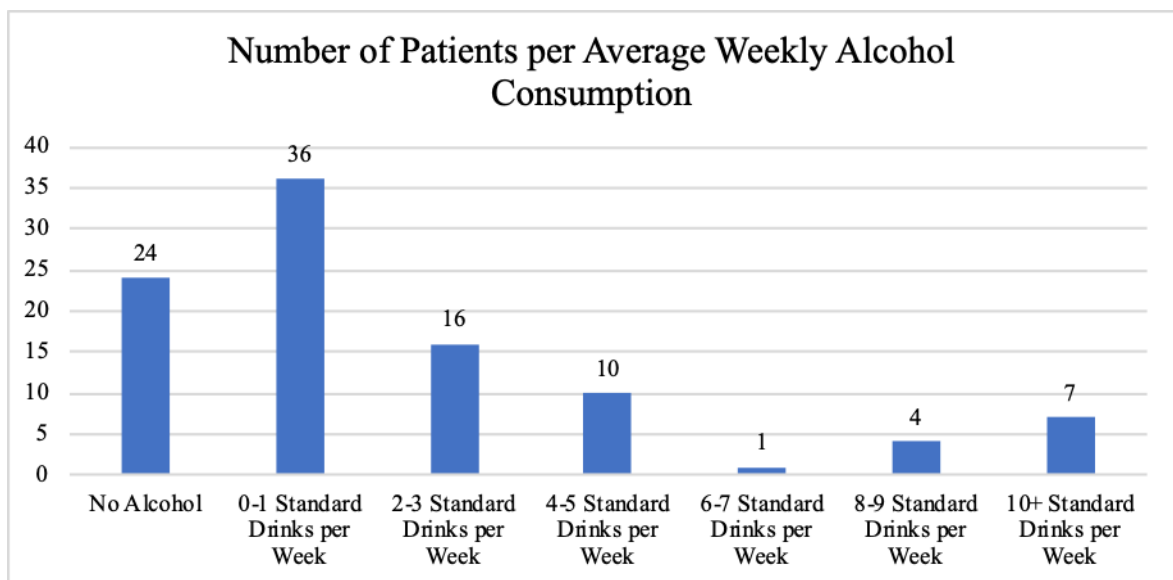
For follow up, the patient had the option to schedule an in-office appointment to review data and discuss results or send the data to the provider through the EPIC MyHealth Tracker system. The MyHealth Tracker system allowed the patient to input blood pressure data into their medical record, which automatically sends to the primary care provider. Upon receipt of the data, the primary care provider is able to calculate the mean home blood pressure. For patients already on anti-hypertensive medication, a normal or elevated blood pressure reading was considered controlled hypertension; a blood pressure in any hypertensive category was considered uncontrolled hypertension. For patients who had never been diagnosed with high blood pressure, the mean home blood pressure measurement allowed the primary care provider to diagnose hypertensive phenotype: normotension or elevated blood pressure, sustained hypertension, white coat hypertension, or masked hypertension. All patients who participated in the quality improvement project were given recommendations on lifestyle changes. Pharmacologic intervention was recommended according to the AHA and ACC 2017 guideline if indicated. The device was then returned to the clinic by the patient. Any saved data was cleared from the device. The machine, cuff, and tubing were wiped down with Sani-wipes, per policy.

## CHAPTER 4: RESULTS

There were 114 patients who met the inclusion criteria for home blood pressure monitoring between January 2, 2019 and August 31, 2019. Of these patients, 16 were excluded from data analysis because they were still under possession of the clinic cuffs upon data collection.

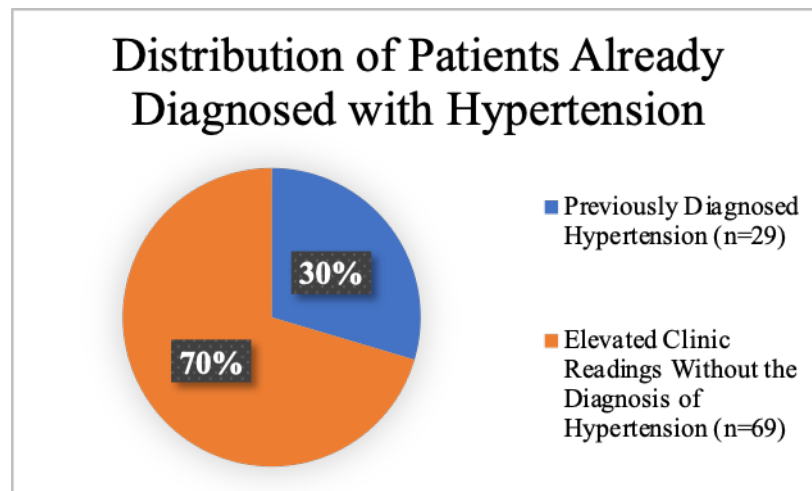
### Sample Demographics

Data was obtained from 98 patients who participated in the quality improvement project. The age range was between 23 and 66 years of age, with a mean age of 44 (SD = 9.29). There were 10 female and 88 male participants. Of the sample, there were 7 patients who were current cigarette smokers, 14 former smokers, and 77 non-smokers. The BMI ranged from 16.54 to 42.69, with a mean of 27.76 (SD = 4.77). Alcohol intake varied (see Figure 1).



*Figure 1.* Number of patients categorized by their reported average weekly alcohol consumption in standard drinks per week.

Of the 98 participants, 30% (n=29) already had the diagnosis of hypertension and were on blood pressure medication while 70% (n=69) had never been diagnosed with hypertension (see Figure 2).



*Figure 2.* Number of patients previously diagnosed with hypertension versus number of patients with elevated blood pressure readings without the diagnosis of hypertension.

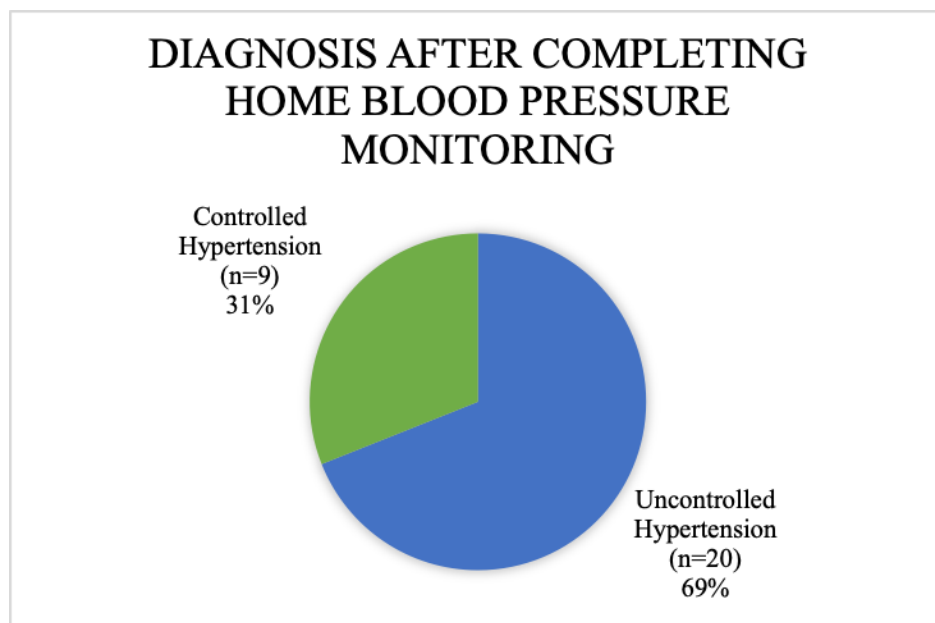
### Data Analysis

Patients who already the diagnosis of hypertension and were on anti-hypertensive medications were given home blood pressure monitors to assess for treatment control. Patients who had never been diagnosed with hypertension were given home blood pressure cuffs to confirm hypertensive phenotype. Therefore, data analyses between these two groups were performed separately.

#### Patients Already Diagnosed with Hypertension

Home blood pressure monitoring was implemented in 29 patients already diagnosed with hypertension to assess for treatment control. After home blood pressure monitoring, 31% (n=9) had controlled hypertension and 69% (n=20) had uncontrolled hypertension (see Figure 3). The patients with controlled

hypertension were advised to continue their current medication regimen and lifestyle modifications were reinforced. All 20 patients who had uncontrolled hypertension agreed to a medication dose change.



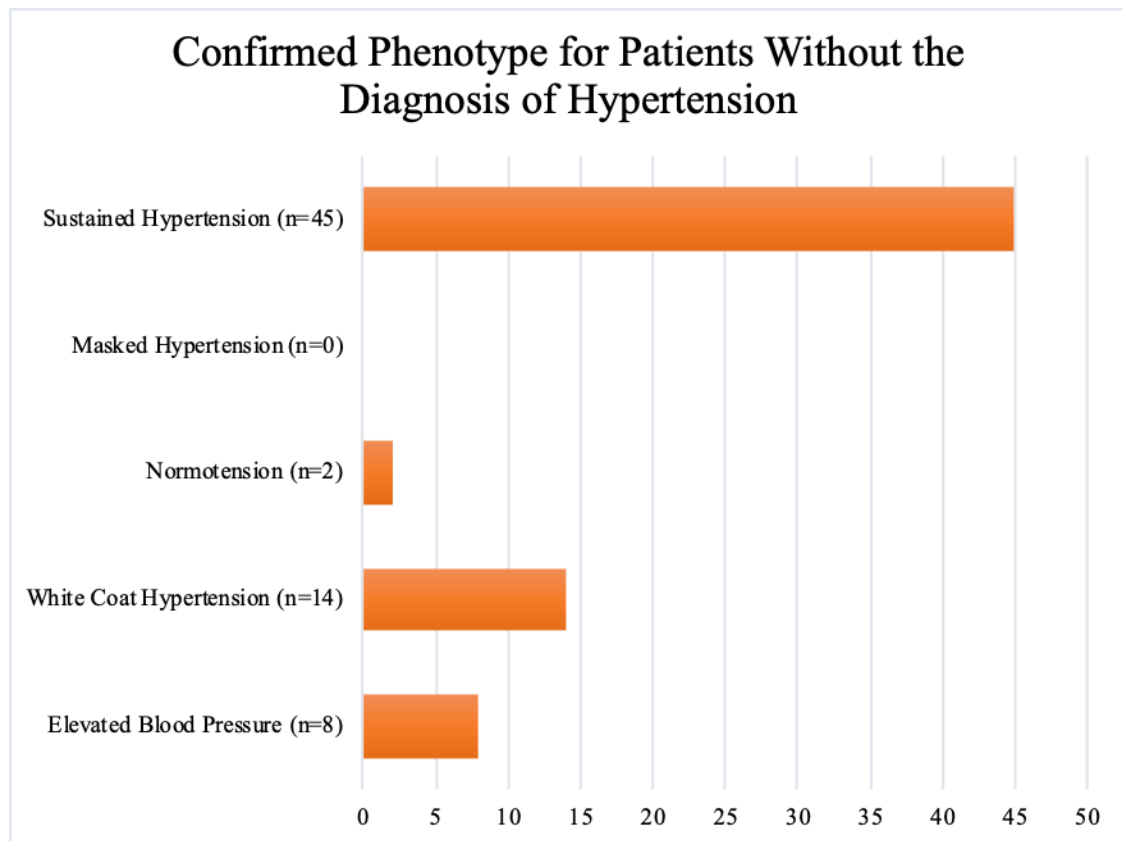
*Figure 3.* Of the patients already diagnosed with hypertension, the number of patients with controlled hypertension versus uncontrolled hypertension after completion of home blood pressure monitoring.

The number of days was documented from the patient's clinic visit to when a diagnosis and treatment plan was made. There was a clear outlier of 140 days for unknown reason. Removing this outlier, the time (days) to treatment intervention ranged from 3 to 35 day, with a mean (days) of 12.7 (SD = 8.27). The median was 11 days from clinic visit to diagnosis and treatment plan.

### **Patients Without the Diagnosis of Hypertension**

Home blood pressure monitoring was implemented in 69 patients who had never been diagnosed with hypertension. After home blood pressure monitoring, 65% (n=45) had sustained hypertension, 20% (n=14) had white coat hypertension,

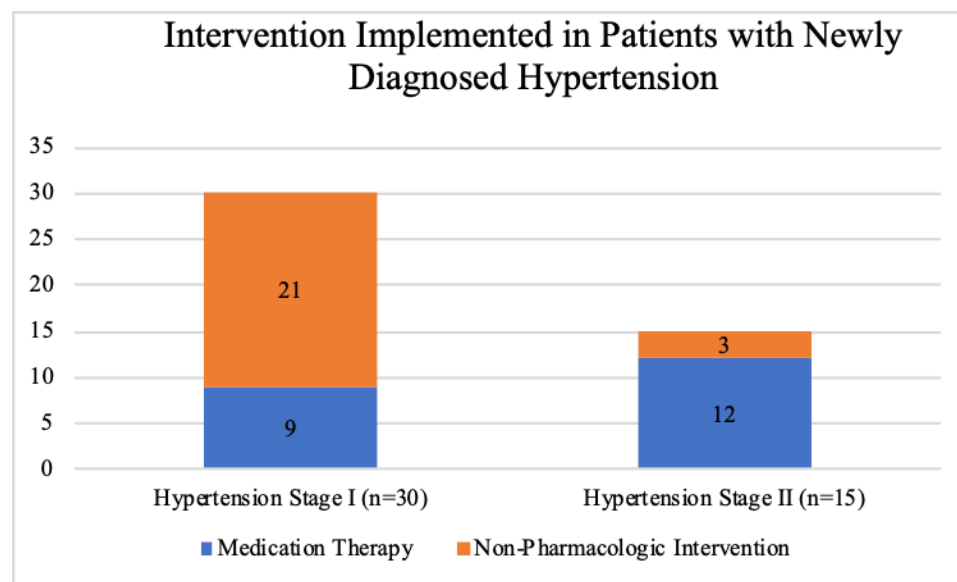
and 12% (n=8) had elevated blood pressure or prehypertension (see Figure 4). No patients had masked hypertension. Two patients were classified to have normotension because they had elevated blood pressure readings at their clinic visit with a normal mean home blood pressure reading.



*Figure 4.* Patients without the diagnosis of hypertension categorized by hypertensive phenotype after the home blood pressure monitoring intervention.

There were 45 patients that were newly diagnosed with hypertension after home blood pressure monitoring was completed. Of these patients, 67% (n=30) had Hypertension Stage 1 and 33% (n=15) had Hypertension Stage 2. Of the patients diagnosed with Hypertension Stage 1, 9 patients agreed to implement medication therapy in addition to lifestyle modifications, and 21 patients opted to work on lifestyle modifications with agreement to re-evaluate the treatment plan in

3 to 6 months (see Figure 5). The time (days) from clinic visit to treatment intervention ranged from 6 to 70 days, with a mean (days) of 16.8 (SD = 13.41), and a median of 14 days. In the patients diagnosed with Hypertension Stage 2, 12 patients agreed to implement medication therapy in addition to lifestyle modifications, and 3 patients opted to work on lifestyle modifications with agreement to re-evaluate the treatment plan in 3 months. The time (days) from clinic visit to treatment intervention ranged from 4 to 34 days, with a mean (days) of 11.73 (SD = 8.67), and a median of 7 days (see Figure 5).



*Figure 5.* Number of patients newly diagnosed with hypertension according to stage, and the treatment plan implemented after home blood pressure monitoring was performed.

## CHAPTER 5: DISCUSSION AND CONCLUSION

### **Discussion**

Implementation of home blood pressure monitoring increased awareness of the importance of hypertension and allowed for education of risk reduction strategies in all 116 patients who met the inclusion criteria for the quality improvement project. All patients who participated took away an understanding of what their blood pressure readings meant and how to make healthy lifestyle choices to reduce their cardiovascular risk.

Home blood pressure monitoring was used to assess for treatment control in patients already diagnosed with hypertension. All of the patients on anti-hypertensive medications diagnosed with uncontrolled hypertension agreed to a medication dose change. This suggests that home blood pressure monitoring was not only effective in assessing for treatment control, but it helped allow the patient to recognize the need for treatment adjustment to improve control.

Home blood pressure monitoring was also used to evaluate hypertensive phenotype in patients undiagnosed with hypertension. Home blood pressure was very useful in verifying the hypertensive phenotype in patients with sustained hypertension and white coat hypertension. Of the 69 patients undiagnosed with hypertension, over half of them (65%, n=45) were confirmed to have sustained hypertension. The percentage of patients diagnosed with white coat hypertension (20%) was consistent with the epidemiologic data estimate of 15% to 30% of the United States population having white coat hypertension. Furthermore, of the 45 patients newly diagnosed with hypertension, home blood pressure monitoring prompted 46% (n=21) to initiate medication therapy. This suggests that home



blood pressure monitoring may have had a positive role in patient recognition and acceptance of diagnosis.

The most profound impact of providing patients with home blood pressure monitors was the turnaround time from clinic visit to diagnosis and treatment plan. Anecdotally, in the investigator's practice, it could take months to years to confirm whether or not a patient had sustained hypertension versus white coat hypertension prior to implementation of this quality improvement project. By providing a patient with a clinic loaned blood pressure device, a diagnosis and treatment plan was made, on average, within two weeks.

### **Limitations**

This was a quality improvement project; therefore, the author is unable to statistically quantify the significance of findings. It was made very clear to CSU Fresno and Stanford School of Medicine that the undertaking was a quality improvement project with the purpose of implementing a data-guided intervention to bring immediate improvements in health delivery as opposed to research designed to contribute to generalizable knowledge. Because this was not a research study, the investigator is unable to correlate any associations between hypertension and alcohol consumption, BMI, or cigarette smoking.

Of the 114 patients who participated in the project, 16 of them were excluded because they still possessed the clinic cuffs at the start of data collection. Unfortunately, due to limited overhead, it was very difficult to track and request the return of these cuffs. Project data did not include the patients who chose to use their own home blood pressure devices. Lastly, Stanford School of Medicine sponsored 30 Omron blood pressure devices to implement the quality improvement project; therefore, for clinics interested in replicating the project,

there may be a cost barrier to obtain a supply of blood pressure devices for their clinic.

### **Future Recommendations**

The ability to monitor blood pressure readings outside of the clinic environment is continuously developing. With the push toward home blood pressure or ambulatory blood pressure monitoring, the diagnosis of hypertension depends on blood pressure variation throughout the day. In addition to ambulatory and home blood pressure monitoring, there are devices available that have the capacity to automatically transmit blood pressure reading directly into the patient's medical record. There are newer devices yet to be FDA approved where the patient wears a patch on their chest that can monitor their blood pressure, heart rhythm, and their blood oxygen saturation

This quality improvement project alone has great potential for expansion. The positive results have already prompted interest for sponsorship of more blood pressure devices. Future analyses can focus on provider and patient attitudes regarding home blood pressure monitoring. Investigation of home blood pressure monitoring in guiding anti-hypertensive treatment is also promising. The United States healthcare system is complex and rapidly evolving as more and more clinics are increasing services through telemedicine. Several patients in this project chose to report their home blood pressure readings to the provider through the MyHealth tracker; it is possible to create a fully-telehealth workflow for blood pressure management.

### **Conclusion**

Management of hypertension is a public health challenge. Without home blood pressure monitoring, it is impossible to correctly diagnose and treat

hypertension, which is essential for hypertension management. Providing patients with a home blood pressure monitor is a simple and effective way to assess for treatment control in patients already diagnosed with hypertension and to validate hypertensive phenotype in patients undiagnosed with hypertension, particularly with white coat hypertension and sustained hypertension. Furthermore, it allows the patients to become active participants in their health and increases awareness of the silent killer known as hypertension. Providing home blood pressure monitors as a screening tool for hypertension has the potential to reduce morbidity and mortality, reduce economic burden, and contribute to national quality initiatives that contribute to the overall health of the nation.

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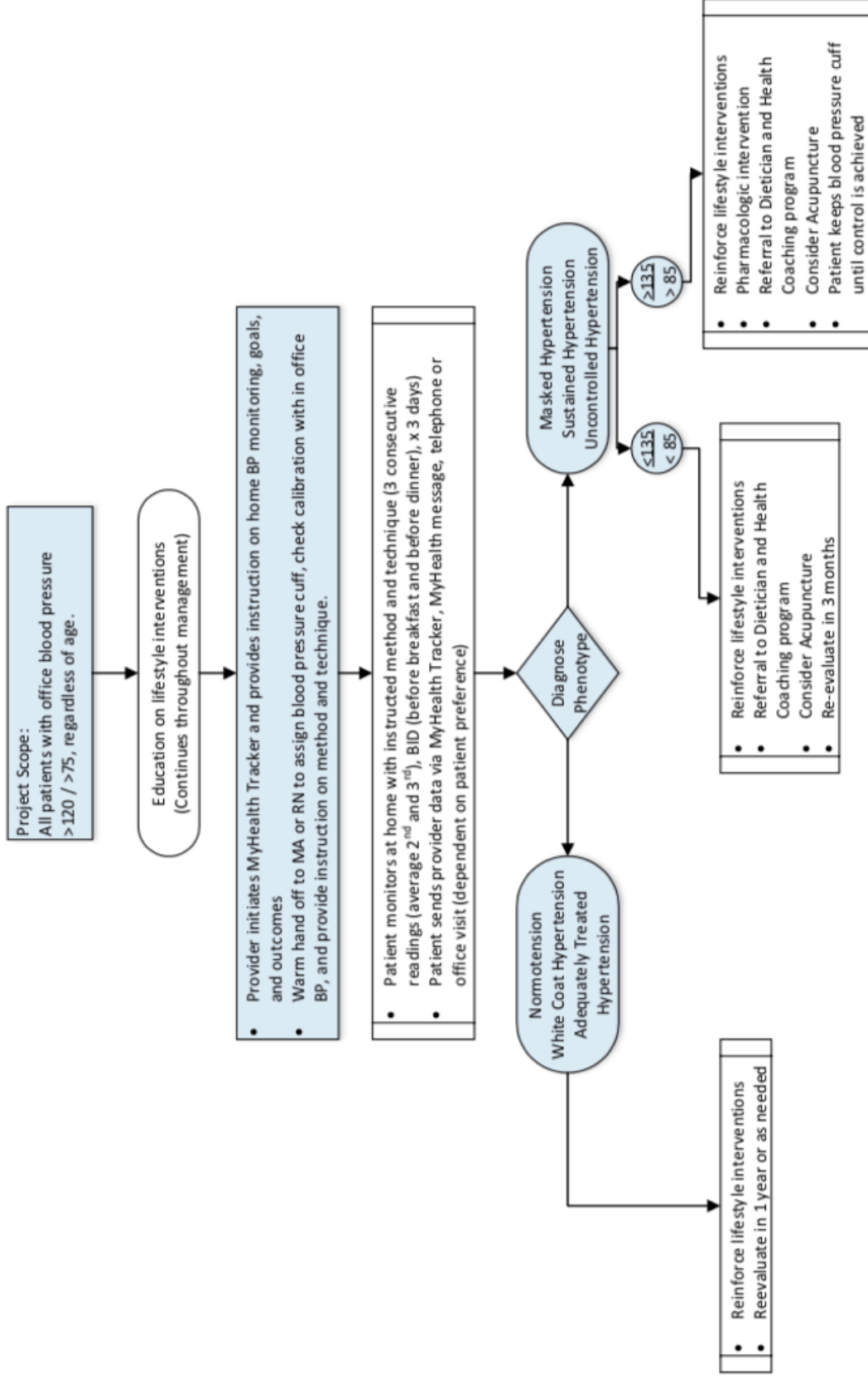
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## APPENDICES

### APPENDIX A: HYPERTENSION SCREENING WORKFLOW



UPON CUFF RETURN, MA OR RN CLEARS ANY SAVED DATA FROM DEVICE AND WIPES EQUIPMENT PER POLICY .